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(54) Title: **COMPUTER-AIDED METHODS, SYSTEMS, AND APPARATUSES FOR SHOULDER ARTHROPLASTY**

(57) Abstract: A method for performing shoulder arthroplasty or hemiarthroplasty is provided. The method includes generating navigational reference information relating to position and orientation of a body part forming at least a portion of the shoulder joint. The reference information may be stored in a computer. Navigational references are attached to the body part and an object. Information is received regarding the position and orientation of the object with respect to the body part and the object is navigated according to this information. The body part may be modified using the object and the modification may be displayed on a monitor associated with the computer. The navigational references may be used to track a shoulder arthroplasty trial component. Information is received regarding the position and orientation of the trial component with respect to the body part. This information is used to navigate the trial component to the body part.

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## COMPUTER-AIDED METHODS, SYSTEMS, AND APPARATUSES FOR SHOULDER ARTHROPLASTY

### RELATED APPLICATION

5       The present application claims priority to U.S. Provisional Serial No. 60/564,162, entitled "Image Guided Surgery for Shoulder Arthroplasty," filed on April 21, 2004, the contents of which are incorporated herein by reference.

### FIELD OF THE INVENTION

10       The invention relates to computer-aided surgery, and more particularly relates to methods, systems, and apparatuses for providing computer-aided surgical navigation systems for shoulder arthroplasty.

### BACKGROUND

15       Many surgical procedures require a wide array of instrumentation and other surgical items. Such items may include, but are not limited to: sleeves to serve as entry tools, working channels, drill guides and tissue protectors; scalpels; entry awls; guide pins; reamers; reducers; distractors; guide rods; endoscopes; arthroscopes; saws; drills; screwdrivers; awls; taps; osteotomes,  
20       wrenches, trial implants and cutting guides. In many surgical procedures, including orthopedic procedures, it may be desirable to associate some or all of these items with a guide and/or handle incorporating a navigational reference, allowing the instrument to be used with a computer-aided surgical navigation system.

25       Several manufacturers currently produce computer-aided surgical navigation systems. The TREON™ and ION™ systems with FLUORONAV™ software manufactured by Medtronic Surgical Navigation Technologies, Inc. are examples of such systems. The BrainLAB VECTORVISION™ system is another example of such a surgical navigation system. Systems and processes for  
30       accomplishing computer-aided surgery are also disclosed in USSN 10/084,012, filed February 27, 2002 and entitled "Total Knee Arthroplasty Systems and Processes"; USSN 10/084,278, filed February 27, 2002 and entitled "Surgical

Navigation Systems and Processes for Unicompartmental Knee Arthroplasty"; USSN 10/084,291, filed February 27, 2002 and entitled "Surgical Navigation Systems and Processes for High Tibial Osteotomy"; International Application No. US02/05955, filed February 27, 2002 and entitled "Total Knee Arthroplasty Systems and Processes"; International Application No. US02/05956, filed February 27, 2002 and entitled "Surgical Navigation Systems and Processes for Unicompartmental Knee Arthroplasty"; International Application No. US02/05783 entitled "Surgical Navigation Systems and Processes for High Tibial Osteotomy"; USSN 10/364,859, filed February 11, 2003 and entitled "Image Guided Fracture Reduction," which claims priority to USSN 60/355,886, filed February 11, 2002 and entitled "Image Guided Fracture Reduction"; USSN 60/271,818, filed February 27, 2001 and entitled "Image Guided System for Arthroplasty"; and USSN 10/229,372, filed August 27, 2002 and entitled "Image Computer Assisted Knee Arthroplasty", the entire contents of each of which are incorporated herein by reference as are all documents incorporated by reference therein.

These systems and processes use position and/or orientation tracking sensors such as infrared sensors acting stereoscopically or other sensors acting in conjunction with navigational references to track positions of body parts, surgery-related items such as implements, instrumentation, trial prosthetics, prosthetic components, and virtual constructs or references such as rotational axes which have been calculated and stored based on designation of bone landmarks. Sensors, such as cameras, detectors, and other similar devices, are typically mounted overhead with respect to body parts and surgery-related items to receive, sense, or otherwise detect positions and/or orientations of the body parts and surgery-related items. Processing capability such as any desired form of computer functionality, whether standalone, networked, or otherwise, takes into account the position and orientation information as to various items in the position sensing field (which may correspond generally or specifically to all or portions or more than all of the surgical field) based on sensed position and orientation of their associated navigational references, or based on stored position and/or orientation information. The processing functionality correlates this position and orientation information for each object with stored information,

such as a computerized fluoroscopic imaged file, a wire frame data file for rendering a representation of an instrument component, trial prosthesis or actual prosthesis, or a computer generated file relating to a reference, mechanical, rotational or other axis or other virtual construct or reference. The processing  
5 functionality then displays position and orientation of these objects on a rendering functionality, such as a screen, monitor, or otherwise, in combination with image information or navigational information such as a reference, mechanical, rotational or other axis or other virtual construct or reference. Thus, these systems or processes, by sensing the position of navigational references, can  
10 display or otherwise output useful data relating to predicted or actual position and orientation of surgical instruments, body parts, surgically related items, implants, and virtual constructs for use in navigation, assessment, and otherwise performing surgery or other operations.

Some of the navigational references used in these systems may emit or  
15 reflect infrared light that is then detected by an infrared camera. The references may be sensed actively or passively by infrared, visual, sound, magnetic, electromagnetic, x-ray or any other desired technique. An active reference emits energy, and a passive reference merely reflects energy. Some navigational references may have markers or fiducials that are traced by an infrared sensor to  
20 determine the position and orientation of the reference and thus the position and orientation of the associated instrument, item, implant component or other object to which the reference is attached.

In addition to navigational references with fixed fiducials, modular fiducials, which may be positioned independent of each other, may be used to reference  
25 points in the coordinate system. Modular fiducials may include reflective elements which may be tracked by two, sometimes more, sensors whose output may be processed in concert by associated processing functionality to geometrically calculate the position and orientation of the item to which the modular fiducial is attached. Like fixed fiducial navigational references, modular  
30 fiducials and the sensors need not be confined to the infrared spectrum—any electromagnetic, electrostatic, light, sound, radio frequency or other desired technique may be used. Similarly, modular fiducials may "actively" transmit

reference information to a tracking system, as opposed to "passively" reflecting infrared or other forms of energy.

5 Navigational references useable with the above-identified navigation systems may be secured to any desired structure, including the above-mentioned surgical instruments and other items. The navigational references may be secured directly to the instrument or item to be referenced. However, in many instances it will not be practical or desirable to secure the navigational references to the instrument or other item. Rather, in many circumstances it will be preferred to secure the navigational references to a handle and/or a guide adapted to receive the instrument or other item. For example, drill bits and other rotating instruments cannot be tracked by securing the navigational reference directly to the rotating instrument because the reference would rotate along with the instrument. Rather, a preferred method for tracking a rotating instrument is to associate the navigational reference with the instrument or item's guide or handle.

15 Computer-aided surgical navigation systems have been developed for various surgeries, but currently none exists for shoulder arthroplasty or hemiarthroplasty that includes features according to the present invention.

20 One of the leading causes for revision after shoulder arthroplasty is misalignment of the implant. Currently, instrumentation design limits alignment of the humeral resection to average values for inclination and version. While some instrumentation designs allow for adjustability of inclination and offset, assessment is still made qualitatively. Also, surgeons often use visual landmarks, or "rules of thumb," which can be misleading due to anatomical variability.

25 Another problem arising in shoulder arthroplasty is that surgeons cannot resurface the glenoid due to a lack of exposure. Exposure in shoulder arthroplasty is limited due to the extensive amount of soft tissue surrounding the shoulder compartment. Because of this problem, surgeons may be able to perform only a hemiarthroplasty in which only the humeral head is replaced.

Yet another problem unique to shoulder arthroplasty is the difficulty in determining the thickness of the scapula. Such a determination is necessary to prevent breakthrough during preparation of the glenoid.

5 In fracture situations, it is difficult to determine the inferior/superior position of the humeral head due to the absence of landmarks. Malpositioning of the humeral head can lead to instability of the shoulder and even dislocation.

The surgeon also relies on instrumentation to predict the appropriate size for the humerus and the glenoid instead of the ability to intraoperatively template the appropriate size of the implants for optimal performance.

10 Another challenge for surgeons is soft tissue balancing after the implants have been positioned. Releasing some of the soft tissue attachment points can change the balance of the shoulder; however, the multiple options can be confusing for many surgeons. In revision shoulder arthroplasty, many of the visual landmarks are no longer present, making alignment and restoration of the  
15 joint line difficult.

Thus, what is needed are systems and processes that allow a surgeon to use patient-specific measurements to determine proper alignment of implants and appropriate revision in shoulder arthroplasty.

Also needed are systems and processes that assist in the appropriate  
20 placement of shoulder arthroplasty components and in the evaluation of that placement. Systems and methods for performing soft tissue balancing in shoulder arthroplasty are also needed.

Also needed are systems and methods that address some or all of the problems mentioned above.

25

## SUMMARY

Some embodiments of the invention include a method for performing shoulder arthroplasty or hemiarthroplasty surgical operations on portions of a shoulder joint. The method includes:

- 30 (a) attaching at least one first navigational reference capable of being tracked by a navigational sensor to a body part forming at least a portion of the shoulder joint,

- (b) generating navigational reference information relating to position and orientation of the body part,
- (c) storing at least some of the navigational reference information in a computer,
- 5 (d) attaching at least one second navigational reference capable of being tracked by a navigational sensor to a surgical instrument,
- (e) receiving information from the navigational sensor regarding the position and orientation of the surgical instrument with respect to the body part, and
- 10 (f) navigating the surgical instrument relative to the body part according to the position and orientation information.

Other embodiments of the invention include a method for performing shoulder arthroplasty or hemiarthroplasty surgical operations on portions of a shoulder joint. The method includes:

- 15 (a) attaching at least one first navigational reference capable of being tracked by a navigational sensor to a body part forming at least a portion of the shoulder joint,
- (b) generating navigational reference information relating to position and orientation of the body part,
- 20 (c) storing at least some of the navigational reference information in a computer,
- (d) attaching at least one second navigational reference capable of being tracked by a navigational sensor to a surgical instrument,
- (e) receiving information from the second navigational sensor regarding the position and orientation of the surgical instrument with respect to the body part,
- 25 (f) navigating the surgical instrument relative to the body part according to the position and orientation information,
- (g) modifying the body part using the surgical instrument,
- 30 (h) generating and displaying on a monitor associated with the computer information regarding the modification of the body part,

- (i) tracking a trial component using at least one of the navigational sensors,
- (j) receiving information from at least one of the navigational sensor regarding the position and orientation of the trial component with respect to the body part,
- 5 (k) generating and displaying on the monitor associated with the computer a visual image of the trial component properly positioned and oriented relative to the body part, and
- (l) navigating the trial component relative to the body part and attaching the trial component to the body part according to the image.
- 10

Some embodiments of the invention include a method for performing shoulder arthroplasty or hemiarthroplasty surgical operations on portions of a shoulder joint. The method includes:

- (a) attaching at least one first navigational reference capable of being tracked by a navigational sensor to a body part forming at least a portion of the shoulder joint,
- 15 (b) generating navigational reference information relating to position and orientation of a body part forming at least a portion of the shoulder joint,
- (c) storing at least some of the navigational reference information in a computer,
- 20 (d) attaching at least one second navigational reference capable of being tracked by a navigational sensor to a surgical instrument,
- (e) receiving information from the second navigational sensor regarding the position and orientation of the surgical instrument with respect to the body part,
- 25 (f) navigating the surgical instrument relative to the body part according to the position and orientation information,
- (g) modifying the body part using the surgical instrument,
- 30 (h) generating and displaying on a monitor associated with the computer information regarding the modification of the body part,



- (i) tracking a prosthetic component using at least one of the navigational sensors,
- (j) receiving information from at least one of the navigational sensor regarding the position and orientation of the prosthetic component with respect to the body part,
- (k) generating and displaying on the monitor associated with the computer a visual image of the prosthetic component properly positioned and oriented relative to the body part, and
- (l) navigating the prosthetic component relative to the body part and attaching the prosthetic component to the body part according to the image.

Some embodiments of the invention include a method for performing shoulder arthroplasty or hemiarthroplasty surgical operations on portions of a shoulder joint. The method includes:

- (a) attaching at least one first navigational reference capable of being tracked by a navigational sensor to a humerus forming at least a portion of the shoulder joint,
- (b) generating navigational reference information relating to position and orientation of the humerus,
- (c) storing at least some of the navigational reference information in a computer,
- (d) attaching at least one second navigational reference capable of being tracked by a navigational sensor to a humeral reamer,
- (e) receiving information from the navigational sensor regarding the position and orientation of the humeral reamer with respect to the humerus, and
- (f) navigating the humeral reamer relative to the humerus according to the position and orientation information.

Other embodiments of the invention include a method for performing shoulder arthroplasty or hemiarthroplasty surgical operations on portions of a shoulder joint; the method includes:

- (a) attaching at least one first navigational reference capable of being tracked by a navigational sensor to a glenoid fossa forming at least a portion of the shoulder joint,
- 5 (b) generating navigational reference information relating to position and orientation of the glenoid fossa,
- (c) storing at least some of the navigational reference information in a computer,
- (d) attaching at least one second navigational reference capable of being tracked by a navigational sensor to a glenoid reamer,
- 10 (e) receiving information from the navigational sensor regarding the position and orientation of the glenoid reamer with respect to the glenoid fossa, and
- (f) navigating the glenoid reamer relative to the glenoid fossa according to the position and orientation information.

15 Some embodiments of the invention include a method for performing shoulder arthroplasty or hemiarthroplasty surgical operations on portions of a shoulder joint. The method includes:

- (a) attaching at least one first navigational reference capable of being tracked by a navigational sensor to a humerus forming at least a portion of
- 20 the shoulder joint,
- (b) generating navigational reference information relating to position and orientation of the humerus,
- (c) storing at least some of the navigational reference information in a computer,
- 25 (d) attaching at least one second navigational reference capable of being tracked by a navigational sensor to a humeral reamer,
- (e) receiving information from the navigational sensor regarding the position and orientation of the humeral reamer with respect to the humerus,
- 30 (f) navigating the humeral reamer relative to the humerus according to the position and orientation information, and
- (g) attaching a cutting block to the humeral reamer.

Some embodiments of the invention include a method for performing shoulder arthroplasty or hemiarthroplasty surgical operations on portions of a shoulder joint. The method includes:

- 5 (a) attaching at least one first navigational reference capable of being tracked by a navigational sensor to a humerus forming at least a portion of the shoulder joint,
- (b) generating navigational reference information relating to position and orientation of the humerus,
- 10 (c) storing at least some of the navigational reference information in a computer,
- (d) attaching at least one second navigational reference capable of being tracked by the navigational sensor to a humeral reamer,
- (e) receiving information from the navigational sensor regarding the position and orientation of the humeral reamer with respect to the  
15 humerus,
- (f) navigating the humeral reamer relative to the humerus according to the position and orientation information,
- (g) attaching a cutting block to the humeral reamer,
- (h) attaching at least one third navigational reference capable of being  
20 tracked by the navigational sensor to the cutting block, and
- (i) positioning the cutting block in at least one rotational degree of freedom through a range motion with infinite positions in the range; and at least one translational degree of freedom through a range of motion with infinite positions in the range,
- 25 (j) receiving continuous information from the navigational sensor regarding the position and orientation of the cutting block with respect to the humerus or the humeral reamer, wherein the information comprises rotational information in at least one degree of freedom and translational information in at least one degree of freedom.

30 Some embodiments of the invention include a computer-aided surgical navigation system for performing shoulder arthroplasty or hemiarthroplasty. The system includes:

(a) a sensor adapted receive information regarding position and orientation of at least one reference;

(b) a reference adapted to be mounted to a body part forming at least a portion of the shoulder joint;

5 (c) a reference adapted to be mounted to a surgical instrument for use in performing shoulder arthroplasty or hemiarthroplasty;

(d) a processor adapted to receive and store information from the sensor in order to track a position and orientation of the at least one surgical reference with respect to the body part; and

10 (e) a monitor adapted to receive information from the processor in order to display at least some of the navigational reference information and the at least one surgical reference.

In some embodiments of the invention, the body part is the humerus. In other embodiments, the body part is the glenoid.

15 In some embodiments, the surgical instrument is a reamer, a resection guide, a cutting block or a probe. In some more particular embodiments, the surgical instrument is a humeral reamer or a glenoid reamer.

#### BRIEF DESCRIPTION OF THE DRAWINGS

20 FIG. 1 is schematic view showing an environment for using a computer-aided surgical navigation system according to some embodiments of the invention in a shoulder arthroplasty or semiarthroplasty.

FIG. 2 is view of the shoulder, including a humerus and a scapula to which navigational references according to some embodiments of the invention have  
25 been attached.

FIG. 3 shows navigation and placement of a humeral reamer according to some embodiments of the present invention.

FIG. 4 shows navigation and placement of a resection guide and a cutting block according to some embodiments of the present invention.

30 FIG. 5. shows the navigation and reaming the glenoid surface in preparation for a prosthetic glenoid component according to some embodiments of the invention.

FIG. 6 shows navigation and placement of a humeral trial component on a humerus according to some embodiments of the invention.

FIG. 7 shows navigation and placement of a drill guide on the glenoid surface according to some embodiments of the invention.

5        FIG. 8 shows navigation and placement of a glenoid trial component on a glenoid fossa according to some embodiments of the invention.

#### DETAILED DESCRIPTION

This invention will now be described more fully with reference to the  
10 drawings, showing preferred embodiments of the invention. However, this invention can be embodied in many different forms and should not be construed as limited to the embodiments set forth.

Systems and processes according to some embodiments of the invention use computing capacity, including stand-alone and/or networked, to determine  
15 and/or store data regarding spatial aspects of surgically related items and virtual constructs or references, including body parts, implements, instrumentation, trial components, prosthetic components and anatomical, mechanical and rotational axes of body parts. Any or all of these may be physically or virtually connected to or incorporate any desired form of mark, structure, component, or other fiducial or  
20 reference device or technique which allows position and/or orientation of the item to which it is attached to be sensed and tracked, preferably in three dimensions of translations and varying degrees of rotation as well as in time, if desired.

Systems and processes according to some embodiments of the invention employ computing means to calculate and store references axes of body  
25 components such as in shoulder arthroplasty, for example the anatomical axis of the humerus and the retroversion reference axis. From these axes such systems track the position of the instrumentation and osteotomy guides so that bone resections will locate the implant position optimally, usually aligned with the anatomical axis. Furthermore, during trial reduction of the shoulder, the systems  
30 provide feedback on the balancing of the soft tissue in a range of motion and under stresses and can suggest or at least provide more accurate information than in the past about which ligaments the surgeon should release in order to

obtain correct balancing, alignment and stability. Systems and processes according to some embodiments of the present invention can also suggest modifications to implant size, positioning, and other techniques to achieve optimal kinematics. They can also include databases of information regarding tasks such as ligament balancing, in order to provide suggestions to the surgeon based on performance of test results as automatically calculated by such systems and processes.

FIG. 1 is a schematic view showing an environment for using a computer-aided surgical navigation system according to some embodiments of the present invention in a surgery on a shoulder, in this case a shoulder arthroplasty. Systems and processes according to some embodiments of the invention can track various body parts such as humerus 101 and scapula 102 to which navigational sensors 100 may be implanted, attached or associated physically, virtually or otherwise.

Navigational sensors 100 may be used to determine and track the position of body parts, axes of body parts, implements, instrumentation, trial components and prosthetic components. Navigational sensors 100 may use infrared, electromagnetic, electrostatic, light sound, radio frequency or other desired techniques.

The navigational sensor 100 may be used to sense the position and orientation of navigational references 104 and therefore items with which they are associated. A navigational reference 104 can include fiducial markers, such as marker elements, capable of being sensed by a navigational sensor in a computer-aided surgical navigation system. The navigational sensor 100 may sense active or passive signals from the navigational references 104. The signals may be electrical, magnetic, electromagnetic, sound, physical, radio frequency, optical or visual, or other active or passive technique. For example in one embodiment, the navigational sensor 100 can visually detect the presence of a passive-type navigational reference. In an example of another embodiment, the navigational sensor 100 can receive an active signal provided by an active-type navigational reference. The surgical navigation system can store, process and/or output data relating to position and orientation of navigational references

104 and thus, items or body parts, such as 101 and 102 to which they are attached or associated.

In the embodiment shown in FIG. 1, computing functionality 108 such as one or more computer programs can include processing functionality, memory  
5 functionality, input/output functionality whether on a standalone or distributed basis, via any desired standard, architecture, interface and/or network topology. In one embodiment, computing functionality 108 can be connected to a monitor 114 on which graphics and data may be presented to a surgeon during surgery. The monitor 114 preferably has a tactile interface so that the surgeon may point  
10 and click on monitor 114 for tactile screen input in addition to or instead of, if desired, keyboard and mouse conventional interfaces. Additionally, a foot pedal 110 or other convenient interface may be coupled to computing functionality 108 as can any other wireless or wireline interface to allow the surgeon, nurse or  
15 other user to control or direct functionality 108 in order to, among other things, capture position/orientation information when certain components are oriented or aligned properly. Items 112 such as trial components, instrumentation components may be tracked in position and orientation relative to body parts 101 and 102 using one or more navigational references 104.

Computing functionality 108 can, but need not, process, store and output  
20 on monitor 114 various forms of data that correspond in whole or part to body parts 101 and 102 and other components for item 112. For example, body parts 101 and 102 can be shown in cross-section or at least various internal aspects of them such as bone canals and surface structure can be shown using fluoroscopic images. These images can be obtained using an imager 113, such as a C-arm  
25 attached to a navigational reference 104. The body parts, for example, humerus 101 and scapula 102, can also have navigational references 104 attached. When fluoroscopy images are obtained using the C-arm with a navigational reference 104, a navigational sensor 100 "sees" and tracks the position of the fluoroscopy head as well as the positions and orientations of the humerus 101  
30 and scapula 102. The computer stores the fluoroscopic images with this position/orientation information, thus correlating position and orientation of the fluoroscopic image relative to the relevant body part or parts. Thus, when the

humerus 101 and corresponding navigational reference 104 move, the computer automatically and correspondingly senses the new position of humerus 101 in space and can correspondingly move implements, instruments, references, trials and/or implants on the monitor 114 relative to the image of humerus 101.

5 Similarly, the image of the body part can be moved, both the body part and such items may be moved, or the on-screen image otherwise presented to suit the preferences of the surgeon or others and carry out the imaging that is desired. Similarly, when an item 112, such as a stylus, cutting block, reamer, drill, saw, extramedullary rod, intramedullary rod, or any other type of item or instrument, that

10 is being tracked moves, its image moves on monitor 114 so that the monitor 114 shows the item 112 in proper position and orientation on monitor 114 relative to the humerus 101. The item 112 can thus appear on the monitor 114 in proper or improper alignment with respect to the mechanical axis and other features of the humerus 101, as if the surgeon were able to see into the body in order to

15 navigate and position item 112 properly.

The computing functionality 108 can also store data relating to configuration, size and other properties of items 112 such as joint replacement prostheses, implements, instrumentation, trial components, implant components and other items used in surgery. When those are introduced into the field of

20 position/orientation sensor 100, computing functionality 108 can generate and display overlain or in combination with the fluoroscopic images of the body parts 101 and 102, computer generated images of joint replacement prostheses, implements, instrumentation components, trial components, implant components and other items 112 for navigation, positioning, assessment and other uses.

25 Instead of or in combination with fluoroscopic, MRI or other actual images of body parts, computing functionality 108 may store and output navigational or virtual construct data based on the sensed position and orientation of items in the surgical field, such as surgical instruments or position and orientation of body parts. For example, monitor 114 can output a resection plane, anatomical axis,

30 mechanical axis, anterior/posterior reference plane, medial/lateral reference plane, rotational axis or any other navigational reference or information that may be useful or desired to conduct surgery. In the case of the reference plane, for



example, monitor 114 can output a resection plane that corresponds to the resection plane defined by a cutting guide whose position and orientation is being tracked by navigational sensors 100. In other embodiments, monitor 114 can output a cutting track based on the sensed position and orientation of a reamer.

5 Other virtual constructs can also be output on monitor 114, and can be displayed with or without the relevant surgical instrument, based on the sensed position and orientation of any surgical instrument or other item in the surgical field to assist the surgeon or other user to plan some or all of the stages of the surgical procedure.

10 In some embodiments of the present invention, computing functionality 108 can output on monitor 114 the projected position and orientation of an implant component or components based on the sensed position and orientation of one or more surgical instruments associated with one or more navigational references 104. For example, the system may track the position and orientation of a cutting  
15 block as it is navigated with respect to a portion of a body part that will be resected. Computing functionality 108 may calculate and output on monitor 114 the projected placement of the implant in the body part based on the sensed position and orientation of the cutting block, in combination with, for example, the mechanical axis of the humerus and/or the shoulder, together with axes showing  
20 the anterior/posterior and medial/lateral planes. No fluoroscopic, MRI or other actual image of the body part is displayed in some embodiments, since some hold that such imaging is unnecessary and counterproductive in the context of computer aided surgery if relevant axis and/or other navigational information is displayed. Additionally, some systems use "morphed" images that change shape  
25 to fit data points or they use generic graphics or line art images with the data points displayed in a relatively accurate position or not displayed at all. If the surgeon or other user is dissatisfied with the projected placement of the implant, the surgeon may then reposition the cutting block to evaluate the effect on projected implant position and orientation.

30 Additionally, computer functionality 108 can track any point in the navigational sensor 100 field such as by using a designator or a probe 116. The probe also can contain or be attached to a navigational reference 104. The

surgeon, nurse, or other user touches the tip of probe 116 to a point such as a landmark on bone structure and actuates the foot pedal 110 or otherwise instructs the computer 108 to note the landmark position. The navigational sensor 100 "sees" the position and orientation of navigational reference 104  
5 "knows" where the tip of probe 116 is relative to that navigational reference 104 and thus calculates and stores, and can display on monitor 114 whenever desired and in whatever form or fashion or color, the point or other position designated by probe 116 when the foot pedal 110 is hit or other command is given. Thus, probe 116 can be used to designate landmarks on bone structure in  
10 order to allow the computer 108 to store and track, relative to movement of the navigational reference 104, virtual or logical information such as retroversion axis 118, anatomical axis 120 and mechanical axis 122 of scapula 102, humerus 101 and other body parts in addition to any other virtual or actual construct or reference.

15 Systems and processes according to some embodiments of the present invention can communicate with suitable computer-aided surgical systems and processes such as the BrainLAB VectorVision system, the OrthoSoft Navitrack System, the Stryker Navigation system, the FluoroNav system provided by Medtronic Surgical Navigation Technologies, Inc. and software provided by  
20 Medtronic Sofamor Danek Technologies. Such systems or aspects of them are disclosed in U.S. Patent Nos. 5,383,454; 5,871,445; 6,146,390; 6,165,81; 6,235,038 and 6,236,875, and related (under 35 U.S.C. Section 119 and/or 120) patents, which are all incorporated herein by this reference. Any other desired systems and processes can be used as mentioned above for imaging, storage of  
25 data, tracking of body parts and items and for other purposes.

These systems may require the use of reference frame type fiducials which have four, and in some cases five elements, tracked by sensors for position/orientation of the fiducials and thus of the body part, implement, instrumentation, trial component, implant component, or other device or structure  
30 being tracked. Such systems can also use at least one probe which the surgeon can use to select, designate, register, or otherwise make known to the system a point or points on the anatomy or other locations by placing the probe as

appropriate and signaling or commanding the computer to note the location of, for instance, the tip of the probe. These systems also may, but are not required to, track position and orientation of a C-arm used to obtain fluoroscopic images of body parts to which fiducials have been attached for capturing and storage of  
5 fluoroscopic images keyed to position/orientation information as tracked by the sensors. Thus, the monitor can render fluoroscopic images of bones in combination with computer generated images of virtual constructs and references together with implements, instrumentation components, trial components, implant components and other items used in connection with surgery for navigation,  
10 resection of bone, assessment and other purposes.

FIGS. 2-7 are various views associated with shoulder arthroplasty surgery processes according to one embodiment of the invention. FIG. 2 shows a human shoulder, as well as the corresponding the corresponding humerus 101 and scapula 102, to which navigational references 104 have been rigidly attached in  
15 accordance with this embodiment of the invention. Attachment of navigational references 104 preferably is accomplished using structure that withstands vibration of surgical saws and other phenomenon which occur during surgery without allowing any substantial movement of navigational references 104 relative to the body part being tracked by the system.

20 Systems and processes according to various embodiments of the invention can be used with cloud of points-type, registration-type, and other surgical location and preparation techniques and methods. For example, in one prosthetic installation procedure, a surgeon can designate a center of rotation of a patient's humeral head for purposes of establishing the mechanical axis and  
25 other relevant constructs relating to the patient's humerus according to which prosthetic components can ultimately be positioned. Such center of rotation can be established by articulating the humerus 101 within the glenoid 103 or a prosthesis to capture a number of samples of position and orientation information and thus in turn to allow the computer to calculate the average center of rotation.  
30 The center of rotation can be established by using a probe 116 associated with a navigational reference 104, and designating a number of points on the humeral head and thus allowing the computing functionality 108 to calculate the

geometrical center or a center that corresponds to the geometry of points collected. Additionally, graphical representations such as controllably sized circles displayed on the monitor can be fitted by the surgeon to the shape of the humeral head on planar images using tactile input on monitor 114 to designate the centers according to that graphic, such as are represented by the computing functionality 108 as intersection of axes of the circles. Other techniques for determining, calculating or establishing points or constructs in space, whether or not corresponding to bone structure, can be used in accordance with the invention.

10 In another example, a navigational sensor 100 can be used in designation or registration of items that will be used in surgery. Registration simply means ensuring that the computing functionality 108 knows which body part, item or construct corresponds to which navigational reference or references 104, and how the position and orientation of the body part, item or construct is related to the position and orientation of its corresponding navigational reference or references 104 attached to an impactor or other component which is in turn attached to an item. Such registration or designation can be done before or after registering bone or body parts. In one instance, a technician can designate with a probe 116 an item such as an instrument or component 112 to which a navigational 104 reference is attached. A navigational sensor associated with a computer-aided surgical navigational system can "see" the 100 position and orientation of the navigational reference 104 attached to the item and also the position and orientation of the navigational reference 104 attached to the probe 116 whose tip is touching a landmark on the item 112. The technician can designate onscreen or otherwise the identification of the item 112 and then activates the foot pedal 110 or otherwise instructs the computing functionality 108 to correlate the data corresponding to such identification, such as data needed to represent a particular cutting block component for a particular shoulder implant product, with the navigational reference 104 attached to the component. The computer has then stored identification, position and orientation information relating to the navigational reference 104 for the component correlated with the data such as configuration and shape data for the item 112 so that upon

registration, when the navigational sensor 100 can track the item 112 and navigational reference 104 in the infrared field, the monitor 114 can show the cutting block component moving and turning, and properly positioned and oriented relative to the body part or navigational information such as axes which  
5 are also being tracked.

Similarly, the mechanical axis and other axes or constructs of body parts can also be "registered" for tracking by the system. Again, the computer-aided surgical navigational system can employ a fluoroscope to obtain images of the patient's humerus and scapula, including the coracoid process, acromion and  
10 glenoid, or other body parts, and/or it can allow generation of navigational information regarding such parts, such as for example, generation of anatomical axis 120 information which can be displayed with the position and orientation of devices, components and other structures connected to navigational references 104. In the case of obtaining images, the system can correlate such fluoroscopic  
15 images with the position and orientation of the C-arm and the patient anatomy in real time as discussed above with the use of one or more navigational references placed on the body parts before image acquisition and which remain in position during the surgical procedure. Using these axes and constructs and/or images and/or the probe, the surgeon can select and register in the computing  
20 functionality 108 the center of the humeral head and elbow in orthogonal views, usually anterior/posterior and lateral, on a touch screen. The surgeon can use the probe 116 to select any desired anatomical landmarks or references at the operative site of the shoulder or on the skin or surgical draping over the skin, as on the elbow. These points can be registered in three-dimensional space by the  
25 system and can be tracked relative to the navigational references 104 on the patient anatomy which are preferably placed intraoperatively. Although registering points using actual bone structure is one preferred way to establish the axis, a cloud of points approach by which the probe is used to designate multiple points on the surface of the bone structure can be employed, as can  
30 moving the body part and tracking movement to establish a center of rotation as discussed above. Once the center of rotation for the humeral head and the

epicondylar axis have been registered, the computer can calculate, store, and render, and otherwise use data for, the mechanical axis of the humerus.

Any desired axes or other constructs can be created, tracked and displayed, in order to model and generate images and data showing any desired static or kinematic function of the shoulder for any purposes related to shoulder arthroplasty.

After the mechanical axis and other rotation axes and constructs relating to the humerus and scapula are established, instrumentation can be properly oriented to resect or modify bone in order to fit trial components and implant components properly according to the embodiments shown in FIGS. 6-7. Instrumentation such as, for instance, cutting blocks, to which navigational references 104 are mounted, can be employed as shown in FIG. 4. The system can then track instrumentation as the surgeon manipulates it for optimum positioning. In other words, the surgeon can "navigate" the instrumentation for optimum positioning using the system and the monitor. In this manner, instrumentation may be positioned according to the system of this embodiment in order to align the osteotomies to the mechanical and rotational axes or reference axes on an extramedullary rod that does not violate the canal, on an intramedullary rod, or on any other type of rod. The monitor 114 can then also display the instrument such as the cutting block and/or the implant relative to the instrument and the rod during this process, in order, among other things, to select the proper size of implant and perhaps implant type. As the instrument moves, the flexion/extension and internal/external rotation of the relative component position can be calculated and shown with respect to the referenced axes; in the preferred embodiment, this can be done at a rate of six cycles per second or faster. The instrument position is then fixed in the computing functionality 108 and physically and the bone resections are made.

Systems and processes according to embodiments of the invention can be used to track a humeral reamer to create a virtual anatomical axis of the humerus. The anatomical axis can be stored and subsequently used by the computer.

FIG. 3 shows orientation of an humeral reamer 124 to which a navigational reference 104 is attached. The surgeon views the monitor 114 which has an image of the humeral reamer 124 overlain on or in combination with the humerus 101 fluoroscopic image as the two are actually positioned and oriented relative to one another in space.

Computer-aided surgical navigation systems according to embodiments of the invention may also be used to determine the degree of humeral head retroversion, if any. The retroversion reference axis may be determined by determining the orientation of the proximal articular surface or the humerus with respect to the epicondylar axis of the elbow. This information may be used to control rotation.

Once the humeral reamer 124 has been placed, instrumentation can be positioned as tracked in position and orientation by navigational sensor 100 and displayed on monitor 114. Thus, as shown in FIG. 4, a resection guide 128 and a cutting block 126 of the sort used to establish the humeral anterior cut, with its navigational reference 104 attached, is introduced into the field and positioned on the reamer. Because the cutting block 126 corresponds to a particular implant product and can be adjusted and designated on screen to correspond to a particular implant size of that product, the computing functionality 108 can generate and the monitor 114 can display a graphic of the cutting block 126 and a humeral component overlain on the fluoroscopic image. The surgeon can thus navigate and position the cutting block 126 on monitor 114 using not only images of the cutting block 126 on the bone, but also images of a corresponding humeral component which will be ultimately installed. The surgeon can thus adjust the positioning of the physical cutting block 126, and secure it to the reamer 124 in order to resect the anterior of the humerus 101 in order to optimally fit and position the ultimate humeral component being shown on the monitor 114. Other cutting blocks and other resections may be positioned and made similarly on the humerus 101.

In some embodiments of the invention, the cutting block 126 may be navigated as it moves in six degrees of freedom: three translational and three rotational. For each rotational degree of freedom, the cutting block 126 may be

tracked as it moves through a range motion with infinite positions in the range. Likewise, for each translational degree of freedom, the cutting block 126 may be tracked as it moves through a range of motion with infinite positions in the range. In some embodiments, the system receives continuous information from the navigational sensor 100 regarding the position and orientation of the cutting block 126 with respect to the humerus 101 or the humeral reamer 124, wherein the information comprises rotational information in at least one degree of freedom and translational information in at least one degree of freedom. The information may be displayed on the monitor 114, allowing the surgeon immediate and detailed information for positioning the cutting block 126.

In a similar fashion, instrumentation may be navigated and positioned on the glenoid fossa 103 of the scapula 102 and as tracked by navigational sensor 100 and on monitor 114 by images of the cutting block and the implant component.

As shown in FIG. 5 in a total shoulder arthroplasty, a glenoid reamer may be navigated to determine the depth, position and angle of reaming. Subsequently, navigated glenoid instruments are then used to prepare the glenoid to receive a glenoid component trial. Any appropriate glenoid component or component trial may be used, for example, an all-polyethylene glenoid component with three pegs or one keel or with a metal back. Such glenoid components generally have three screw holes on the glenoid base. Depending on the type of glenoid component used, a drill guide 138 or a keel reamer guide may be used to prepare the glenoid for the glenoid component. A navigated drill guide 138 is shown in FIG. 7.

Once resection and modification of bone has been accomplished, implant trials can then be installed and tracked by the system in a manner similar to navigating and positioning the instrumentation, as displayed on the monitor 114. Thus, a humeral component trial and a glenoid component trial may be placed as navigated on monitor 114 using computing functionality 118 generated overlays corresponding to the trials.

During the trial installation process, and also during the implant component installation process, instrument positioning process or at any other desired point



in surgical or other operations according to the invention, the system can transition or segue from tracking a component according to a first navigational reference to tracking the component according to a second navigational reference. Thus, as shown in FIG. 6, the trial humeral component 134 is mounted on an impactor 132 to which is attached a first navigational reference 104. The trial component 134 is installed and positioned using the impactor 132. The computing functionality 108 tracks the position and orientation of the trial component 134 relative to the navigational reference 104 on the impactor 132 (such as by prior registration of the component 134 attached to the impactor) so that it can generate and display the image of the humeral trial component 134 on monitor 114 overlaid on the fluoroscopic image of the humerus 101. At any desired point in time, before, during or after the trial component 134 is properly placed on the humerus 101 to align with anatomical axis and according to proper orientation relative to other axes, the system can be instructed by foot pedal 110 or otherwise to begin tracking the position of the trial component 134 using the second navigational reference 104 attached to the humerus 101 rather than the one attached to the impactor 132. According to the preferred embodiment, the navigational sensor 100 "sees" at this point in time both the navigational references 104 on the impactor 132 and on the humerus 101 so that it already "knows" the position and orientation of the trial component 134 relative to the first navigational reference 104 on the impactor 132 and is thus able to calculate and store for later use the position and orientation of the trial component 134 relative to the second navigational reference 104 on the humerus 101. Once this "handoff" happens, the impactor 132 can be removed and the trial component 134 tracked with the navigational reference 104 on the humerus 101 as part of or moving in concert with the humerus 101. Similar handoff procedures may be used in any other instance as desired in accordance with the present invention.

FIG. 6 shows the placement of a humeral trial component 134 attached to humerus 101. The trial component 134 is attached via impactor 132. As explained above, both the humerus 101 and the impactor 132 have navigational references 104 attached that may be used in tracking and navigating trial component 134.

Similarly, as shown in FIG. 8, a glenoid trial component 136 can be placed on the glenoid 103 and then registered using a probe. A probe may be used to designate features on the glenoid trial component 136 of known coordinates, such as rotational alignment to the glenoid axis, the flexion/extension angle and the version/retroversion angle. As the probe is placed onto each feature, the system is prompted to save that coordinate position so that the system can match the glenoid trial component's 136 feature's coordinates to the saved coordinates. The system then tracks the glenoid trial component 136 relative to the anatomical reference frame.

The system may also indicate the fit of the glenoid keel or pegs within the glenoid before bone preparation is performed to insure that breakthrough to the posterior aspect of the scapula 102 does not occur.

FIG. 8 shows the placement of a glenoid trial component 136 attached to a glenoid 103.

Once the trial components are installed, the surgeon can assess alignment and stability of the components and the joint. During such assessment, in trial reduction, the computing can display on monitor 114 the relative motion between the trial components to allow the surgeon to make soft tissue releases and changes in order to improve the kinematics of the shoulder. The system can also apply rules and/or intelligence to make suggestions based on the information such as what soft tissue releases to make if the surgeon desires. The system can also display how the soft tissue releases are to be made.

During this assessment, the surgeon may conduct certain assessment processes such as external/internal rotation, rotary laxity testing, range of motion testing (external rotation, internal rotation and elevation) and stability testing (anterior, posterior and inferior translation). Thus, in the external/internal rotation test, the surgeon can position the humerus at the first location and press the foot pedal. He then positions the humerus at the second location and once again presses the foot pedal so that the computing functionality has registered and stored two locations in order to calculate and display the rotation and whether it is acceptable for the patient and the product involved. If not, the computer can apply rules in order to generate and display suggestions for releasing ligaments

or other tissue, or using other component sizes or types. Once the proper tissue releases have been made, if necessary, and alignment and stability are acceptable as noted quantitatively on screen about all axes, the trial components may be removed and actual components navigated, installed, and assessed in performance in a manner similar to that in which the trial components were navigated, installed, and assessed.

At the end of the case, all alignment information can be saved for the patient file. This is of great assistance to the surgeon due to the fact that the outcome of implant positioning can be seen before any resectioning has been done on the bone.

The tracking and image information provided by systems and processes according to the present invention facilitate telemedical techniques, because they provide useful images for distribution to distant geographic locations where expert surgical or medical specialists may collaborate during surgery. Thus, systems and processes according to the present invention can be used in connection with computing functionality 108 which is networked or otherwise in communication with computing functionality in other locations, whether by PSTN, information exchange infrastructures such as packet switched networks including the Internet, or as otherwise desire. Such remote imaging may occur on computers, wireless devices, videoconferencing devices or in any other mode or on any other platform which is now or may in the future be capable of rendering images or parts of them produced in accordance with the present invention. Parallel communication links such as switched or unswitched telephone call connections may also accompany or form part of such telemedical techniques. Distant databases such as online catalogs of implant suppliers or prosthetics buyers or distributors may form part of or be networked with computing functionality 108 to give the surgeon in real time access to additional options for implants which could be procured and used during the surgical operation.

The above methods and techniques are provided by way of example only, and other embodiments of the present invention can be used with other surgical location and preparation techniques and methods.

Changes and modifications, additions and deletions may be made to the structures and methods recited above and shown in the drawings without departing from the scope or spirit of the invention and the following claims.

What is claimed is:

1. A method for performing shoulder arthroplasty or hemiarthroplasty surgical operations on portions of a shoulder joint, the method characterized by:
  - 5 (a) attaching at least one first navigational reference capable of being tracked by a navigational sensor to a body part forming at least a portion of the shoulder joint;
  - (b) generating navigational reference information relating to position and orientation of the body part;
  - 10 (c) storing at least some of the navigational reference information in a computer;
  - (d) attaching at least one second navigational reference capable of being tracked by a navigational sensor to a surgical instrument;
  - (e) receiving information from the second navigational sensor regarding  
15 the position and orientation of the surgical instrument with respect to the body part;
  - (f) navigating the surgical instrument relative to the body part according to the position and orientation information;
  - (g) modifying the body part using the surgical instrument;
  - 20 (h) generating and displaying on a monitor associated with the computer information regarding the modification of the body part;
  - (i) tracking a prosthetic component using at least one of the navigational sensors;
  - (j) receiving information from at least one of the navigational sensor  
25 regarding the position and orientation of the prosthetic component with respect to the body part;
  - (k) generating and displaying on the monitor associated with the computer a visual image of the prosthetic component properly positioned and oriented relative to the body part; and
  - 30 (l) navigating the prosthetic component relative to the body part and attaching the prosthetic component to the body part according to the image.

2. The method of claim 1, further characterized in that the surgical instrument comprises at least one of the following: a reamer, a resection guide, a cutting block and a probe.

5

3. The method of claim 1, further characterized in that the body part is the humerus.

4. The method of claim 3, further characterized in that the information received from the navigational sensor comprises information regarding the anatomical axis of the humerus.

10

5. The method of claim 1, further characterized in that the body part is the glenoid fossa.

15

6. The method of claim 5, further characterized in that the information received from the navigational sensor comprises the epicondylar axis of the humerus and the information received is used to determine the retroversion reference axis.

20

7. The method of claim 1, further characterized in that the prosthetic component comprises at least one of the following: a humeral component and a glenoid component.

25

8. The method of claim 1, further characterized in that the navigational reference information is generated by an imager.

9. The method of claim 8, further characterized in that the imager comprises one of the following: a C-arm fluoroscope, a CT scanner, MRI equipment, ultrasound equipment, laser scanning equipment and a probe.

30

10. The method of claim 1, further characterized in that the prosthetic component is a trial component.

11. The method of claim 10, further characterized by:

- 5 (a) removing the trial component from the joint; and  
(b) navigating a prosthetic component using posting and orientation information regarding the trial component.

12. The method of claim 1 or 11, further characterized by:

- 10 (a) performing soft tissue balancing tests while the computing means continues to track the navigational sensor;  
(b) using data generated by the computer to assess alignment and stability of the joint with the trial component attached; and  
(c) releasing soft tissue to adjust alignment and stability.

15 13. A computer-aided surgical navigation system for performing shoulder arthroplasty or hemiarthroplasty, the system characterized by:

- (a) a sensor adapted receive information regarding position and orientation of at least one reference;  
20 (b) a reference adapted to be mounted to a body part forming at least a portion of the shoulder joint;  
(c) a reference adapted to be mounted to a surgical instrument for use in performing shoulder arthroplasty or hemiarthroplasty;  
(d) a processor adapted to receive and store information from the  
25 sensor in order to track a position and orientation of the at least one surgical reference with respect to the body part; and  
(e) a monitor adapted to receive information from the processor in order to display at least some of the navigational reference information and the at least one surgical reference.

30 14. The system of claim 13, further characterized in that the body part is the humerus.

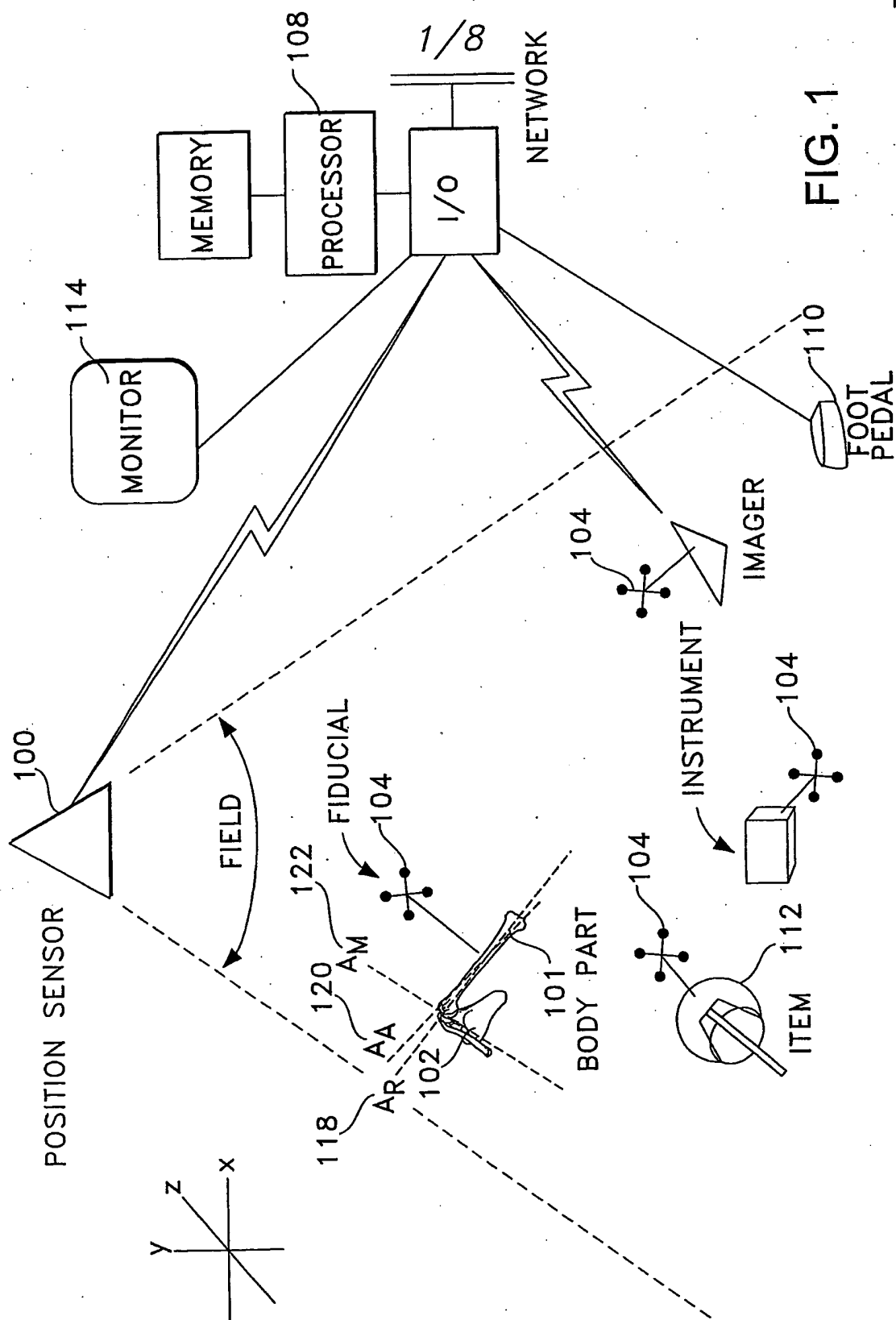
15. The system of claim 13, further characterized in that the body part is the glenoid.

5 16. The system of claim 14, further characterized in that the surgical instrument is a humeral reamer.

17. The system of claim 15, further characterized in that the surgical instrument is a glenoid reamer.

10





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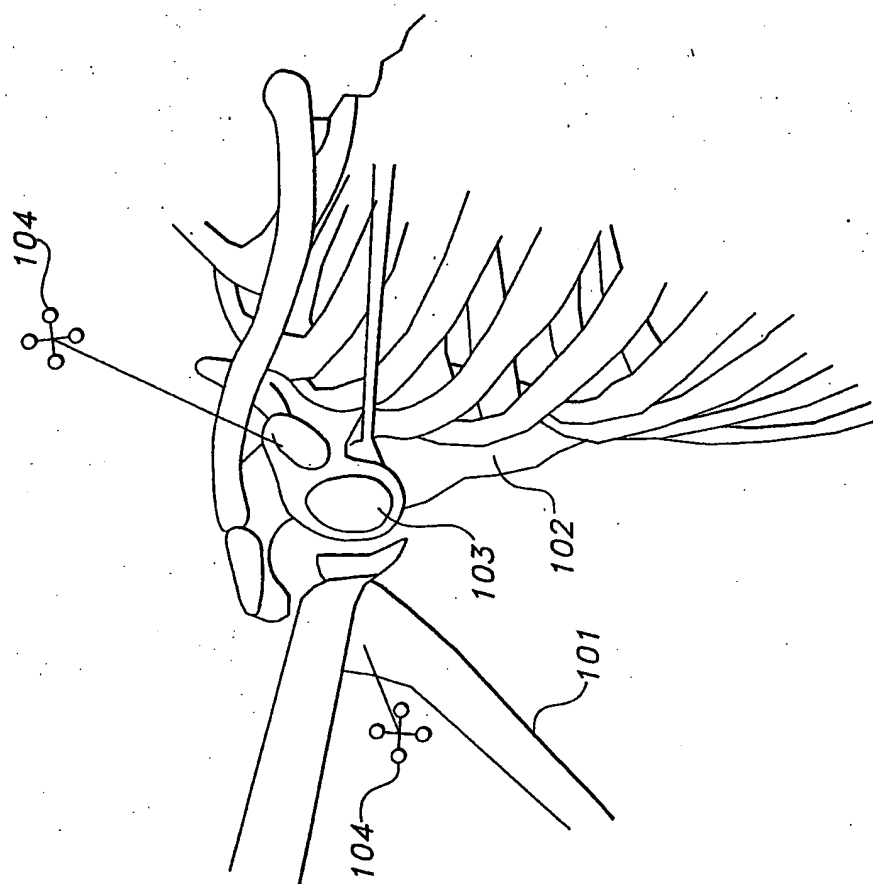


FIG. 2

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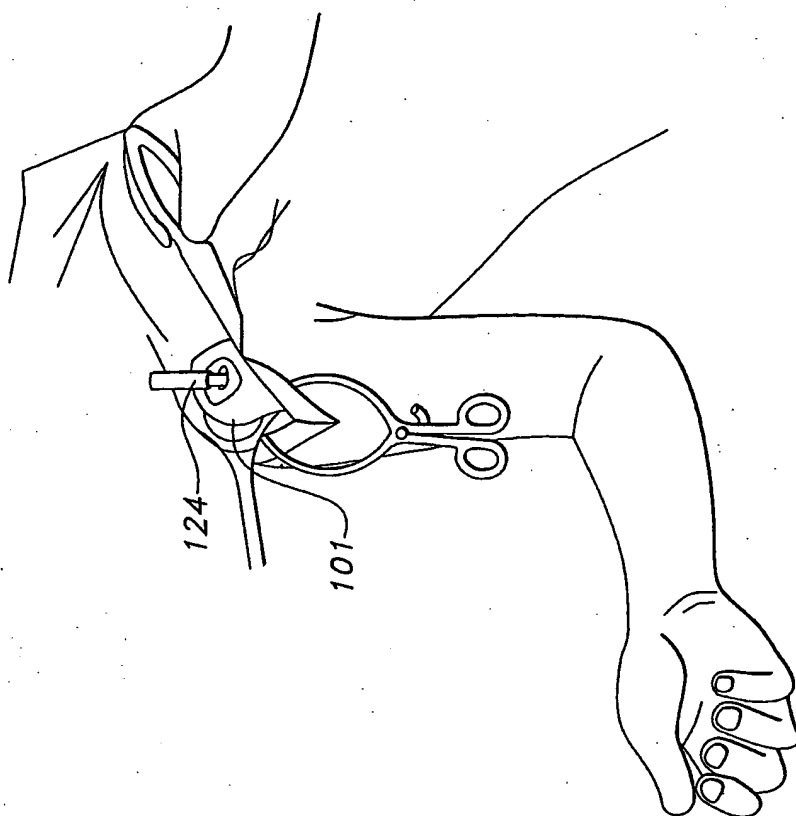


FIG. 3

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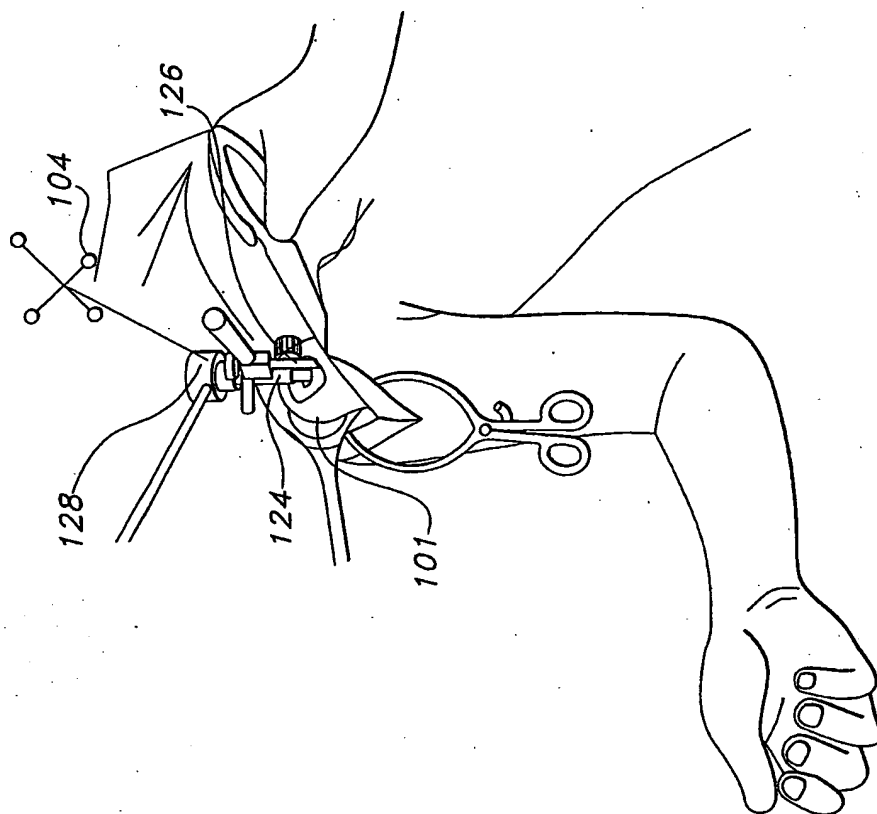


FIG. 4

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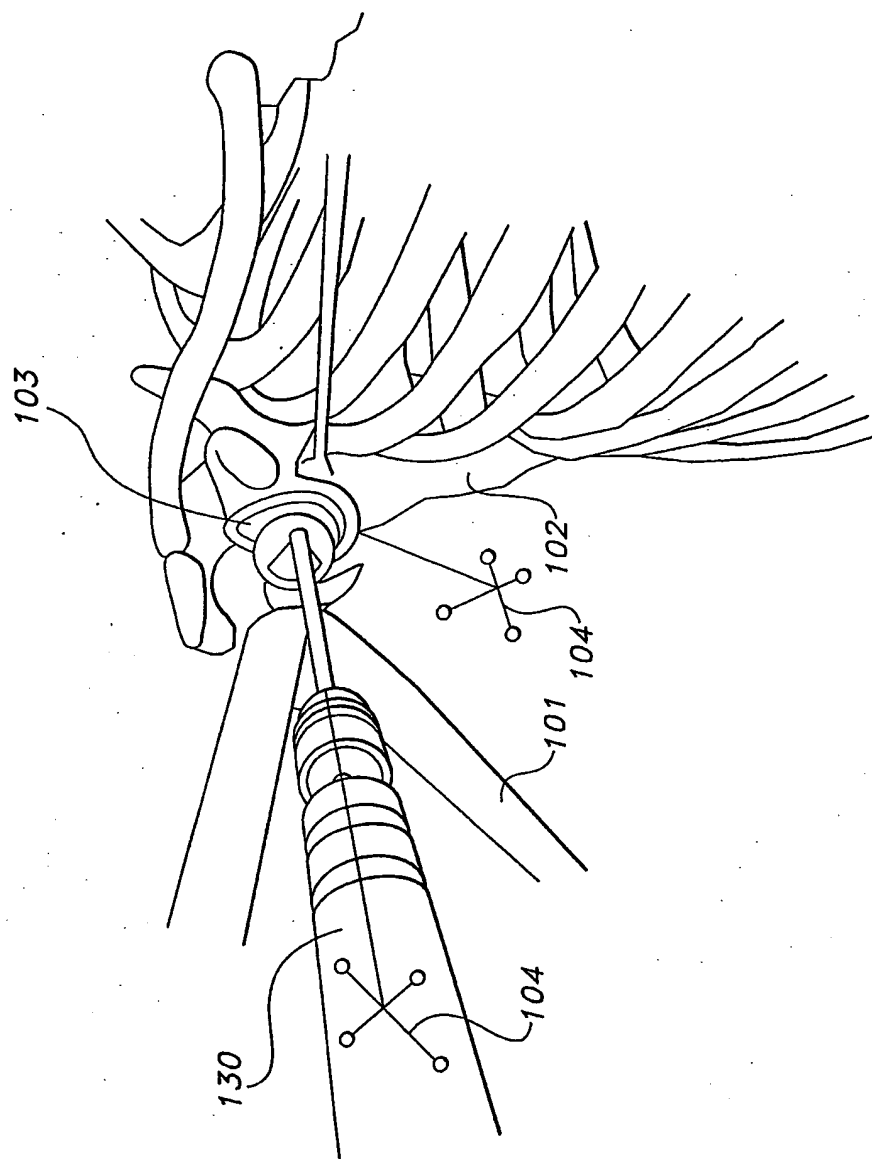


FIG. 5

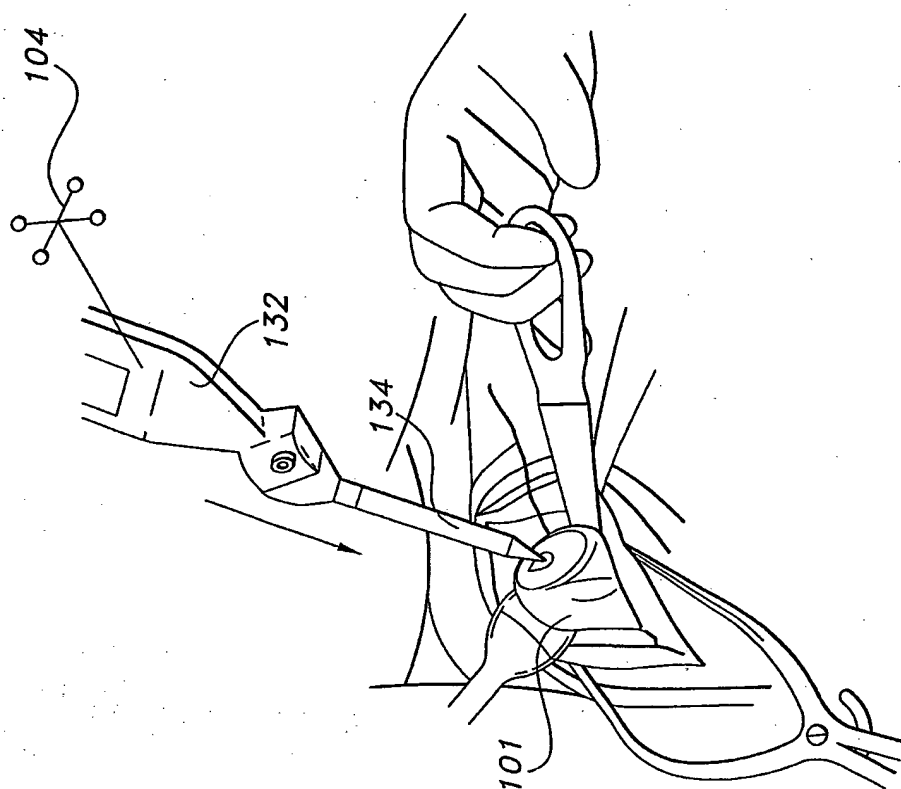


FIG. 6

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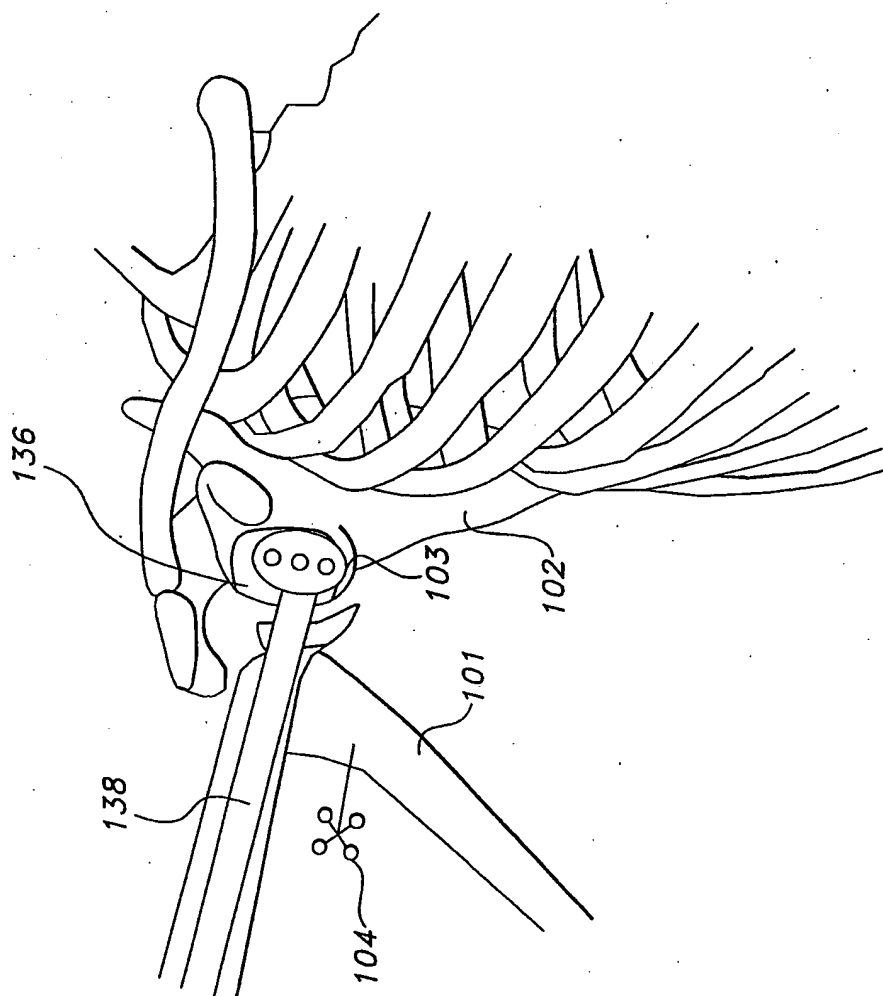


FIG. 7

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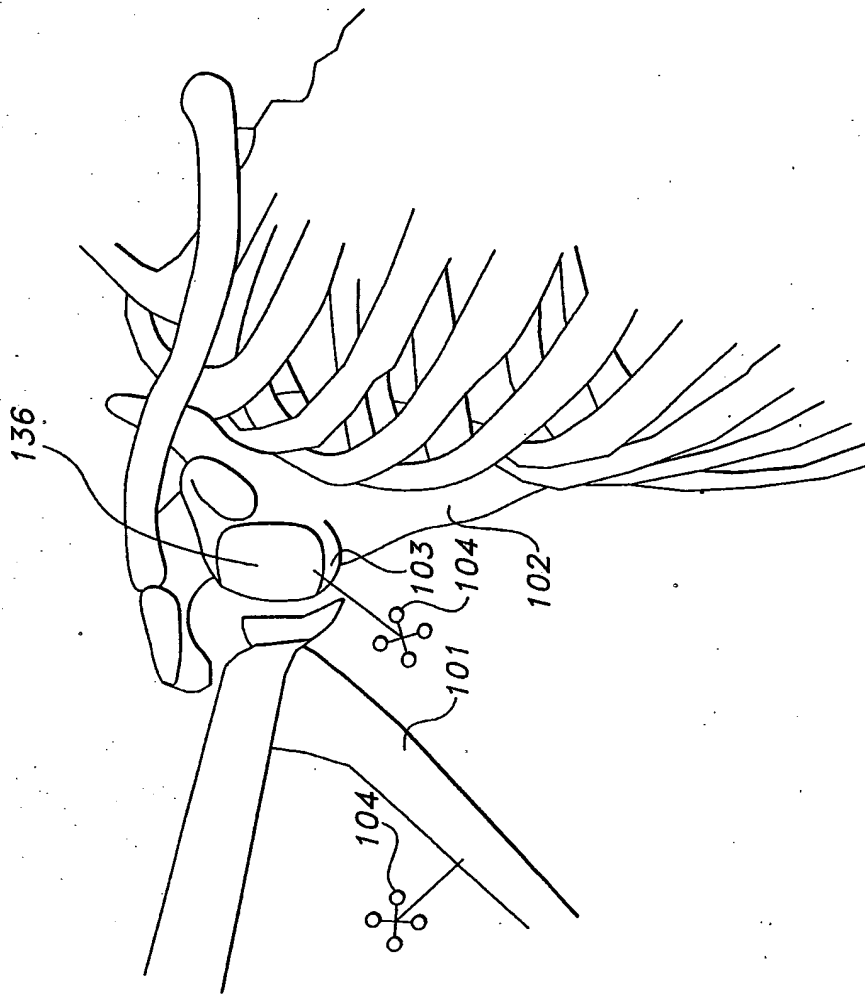


FIG. 8



## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US2005/013416

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/069591 A1 (CARSON CHRISTOPHER PATRICK ET AL) 10 April 2003 (2003-04-10) cited in the application paragraphs '0005!', '0006!; figure 1 paragraph '0003!	13-17
A	WO 03/068090 A (SMITH & NEPHEW, INC; SMOTHERS, CRISTA; KAHLER, DAVID, MARC; TERRILL-GR) 21 August 2003 (2003-08-21) cited in the application page 1; figure 12 page 17, lines 13-29	13, 14, 16

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*A\* document member of the same patent family

Date of the actual completion of the international search

2 September 2005

Date of mailing of the international search report

12/09/2005

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2005/013416

### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-12  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(1v) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/013416

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